

Healthcare Innovation in the 21st Century

David Hankin
Chief Executive Officer
Alfred E. Mann Foundation for Scientific Research
July 26, 2010



What You Just Saw

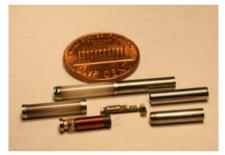
- Study subject/patient Army Colonel
 - Special forces
 - Competitive athlete
 - High spinal cord injury Bicycle vs. Car
 - Doctors reported that prior rehabilitation was ineffective
- Footage from an actual surgery at Walter Reed that occurred on November 5, 2008
 - 3 microstimulator devices were implanted via a minimally procedure
 - 18 months following injury
- Study objective
 - Can rehabilitation using microstimulators strengthen subject's muscles so that he can regain function in his lower extremities?



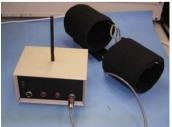
Personification of Innovation







Microstimulator Implant



Charging Station and Coil

System Highlights

68 issued patents and several pending

Needle injection in Dr. office under local reduces costs

 RF communications 100 times per second

Wireless

Walter Reed Army Medical Center Leg Press with no stimulation April 30, 2009



Microstimulator System Designed to Restore Function to Paralyzed Limbs

- ~2% of all Americans (5.6 million people) live with paralysis
 - Christopher Reeves Foundation, 2008
- Predominant Movement Disorders
 - Traumatic brain injury
 - Signature injury from conflicts
 - Stroke
 - ~800,000 per year in US
 - Spinal cord injury
 - ~12-15K per year in US
 - Multiple Sclerosis
 - ~ 400,000 people in US
 - Cerebral palsy
 - ~2 per every 1000 births in the US
- Advanced Prosthesis
 - Replaces less effective surface myoelectric sensors
 - Direct neural control



Patient Access Dependent Upon Regulatory Process

FCC

- Seeking allocation of spectrum on secondary basis
 - Began process in January, 2005
 - Process on-going
- Specific bands require coordination with NTIA
 - Shared spectrum with incumbent users on critical path

FDA

- Engineering of initial versions completed
- 10 years in development at cost of \$110 million
- Human feasibility studies under FDA auspices in stroke, spinal cord injury and traumatic brain injury either completed or planned

CMS

- Insurance reimbursement effort a commercial activity
 - AMF commercial partners will undertake responsibility
- Some precedent for codes and coverage already exist



Healthcare Innovation

- Healthcare innovation should be a national priority
 - Enormous potential
 - Healthcare costs hijacking America
- Advanced signal processing along with the ability to collect, process, assimilate and use data will drive healthcare innovation in this century
- Wireless communications networks are vital to data handling
 - Broadband networks with the capacity to handle massive amounts data at high rates is required
 - Networks must be sufficiently reliable and secure
- Advanced communications platforms must be available to foster healthcare innovation



Disclaimer

 Caution: The Microstimulator System is an Investigational device. Limited by Federal (or USA) law to investigational use, only.



Thank You